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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/752,895	01/07/2004	Victor Witold Jacewicz	P32039-C2	4559

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EXAMINER	
CHANG, CELIA C	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/752,895	JACEWICZ ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This application is a continuation of SN 10/174,237. Claims 1-15 have been canceled by preliminary amendment. Claims 16-35, same as prosecuted in the parent case, are in the case.

2. Claims 18-21 and 32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form. Please note that claims 18-21 are dependent on canceled claims 1 and 2. Correction is required. Claims 32 is a compound claim which depends on a method claim thus is improper. Correction is required.

3. Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims must stand alone to define invention. The incorporation of expressive reference to specification in the claims are considered as failing to particularly point out and distinctly claim the invention under the second paragraph. Revision of the claims to include all the required elements for each claim is required.

4. Claim 35 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diseases which are known to be treatable by paroxetine, does not reasonably provide enablement for the scope of the claim which includes treating and preventing any and all "disorder" a person may suffer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims. The scope of the claim is considered incredible since it treats man from all disorder and prevents man from any unwanted suffering.

Claims 17, 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing paroxetine maleate with a base to acid ration of 1:1.5 (see p.4), does not reasonably provide enablement for a product of paroxetine maleate

(2:1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to how to make the invention commensurate in scope with these claims. No description on what condition must be employed to obtain product with this particular ratio.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 16, 20, 23, 26, 28, 29, 33 are rejected under 35 U.S.C. 102(b) or (e) as being clearly anticipated by Christensen et al. US 4,007,196 or Benneker et al. US 5,874,447 (both cited on 1449).

See Christensen '196, col. 7, lines 1-5, example 2;

Bennecker, et al. '447, col. 8-9, example 5.

The process of crystallizing from solvent of paroxetine base with maleic acid and the crystalline products are disclosed.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20-23, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen et al. US 4,007,196 or Benneker et al. US 5,874,447 (both cited on 1449) in view of Jacewicz et al. GB 2,297,550.

Determination of the scope and content of the prior art (MPEP §2141.01)

Christensen '196 or Benneker et al. '447 disclosed process and products anticipated the base claims as delineated supra.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Christensen '196 or Benneker et al. '447 disclosed all the elements of the base claims **except** the more specific condition such as choices of solvents, employment of seeding were not explicitly described. Jacewicz et al. '550 disclosed a large array of variations can be employed by person having ordinary skill to obtain salts of paroxetine (see whole article, especially example 18, optional seeding and solvent of toluene).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the paroxetine art is in possession of the variations in empirical conditions known to be operable for the field. The picking and choosing of an operable condition within the conventional teaching of the art to obtain maximun production of crystalline paroxetine maleate is an effect oriented modification within the knowledge and operability of the field, thus, is prima facie obvious to person having ordinary skill in the field.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18, 19, 24, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christensen et al. US 4,007,196 or Benneker et al. US 5,874,447 (both cited on 1449) in view of Wang et al. EP 810,224 or murthy et al. CA 2,193,939.

Determination of the scope and content of the prior art (MPEP §2141.01)

Christensen '196 or Benneker et al. '447 disclosed process and products anticipated the crystalline form of paroxetine maleate as delineated supar.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Christensen '196 or Benneker et al. '447 disclosed crystalline form **without** making noncrystalline product of paroxetine maleate. Wang et al. '224 or Murthy et al. '939 disclosed that upon possession of a crystalline paroxetine salt, the sraydrying or melt or rotary drying processes can be employed to obtain the amorphous i.e. non-crystalline form of the product which have better handling properties than the crystalline form (see whole article of both reference).

Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art would be motivated to employing conventional processes for obtaining amorphous salts for the crystalline maleate since amorphous products would offer better handling properties such as conventionally taught in the art.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lassen et al. US 4,745,122 or 4,804,669 in view of Jacewicz et al. GB 2,297,550.

Lassen '669 or 122 disclosed method of treating obesity or pain employing paroxetine maleate (see '699 claims 1 and 4, '122 claims 1 and 7). One having ordinary skill in the art would expect that the paroxetine maleate of the instant claims to operate as the conventionally known salts for the purpose known conventionally treatable by paroxetine as disclosed by Jacewicz et al. '550 (see p.8).

9. Applicants attention is drawn to the two WO 00/01693 and WO 00/35873 recited on PTO-892.

The WO 00/01693 patent claimed the same paroxetine maleate crystalline form which may constitute a 102(e) or (g) reference when the national stage in US is allowed (see US designated).

The WO 00/35873 indicated SmithKline Beecham being the applicant and claimed crystallinsing maleate salt of paroxetine. Applicants are requested to show co-ownership at the time of invention and demarcation of the claims to avoid double patenting. Or since the Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no

effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

10. This is a contiuation of applicant's earlier Application No. 10/174,237. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celia Chang
Primary Examiner
Art Unit 1625

OACS/Chang
Feb. 16, 2006